

**FOI 23/081**

10<sup>th</sup> February 2023

Dear

Thank you for your email dated 31st January 2023, where you requested information held by the MHRA relating to the OpenSAFELY study "Project #64: Short-term safety of COVID-19 vaccines in England 2020/21 – acute venous thromboembolic events".

Over the course of the pandemic, in line with the COVID-19 vaccine safety surveillance strategy, MHRA engaged with multiple academic and clinical research groups, including OpenSAFELY, on research exploring and evaluating safety signals raised in association with the COVID-19 vaccines.

The potential study "Project #64: Short-term safety of COVID-19 vaccines in England 2020/21 - acute venous thromboembolic events" was first considered following the signal of an increased risk of acute thrombotic events with thrombocytopenia in temporal association with the AstraZeneca vaccine in early 2021. At that time other research groups in the UK also initiated studies looking at this risk using both linked national datasets and active data collection. These studies have subsequently been published (e.g. Hippisley-Cox et al. BMJ 2021, Simpson et al. Nat Med. 2021, Whitely et al. PLoS med. 2022, and Pavord et al. NEJM 2021).

Given these other studies were also being progressed, that the patients in OpenSAFELY were a subset of those found in national datasets, and that the additional primary care data available in OpenSAFELY were unlikely to be of further value in identifying cases, the MHRA agreed with OpenSAFELY researchers that the study on neurological events (Project #63) should be prioritised. To date, Project #64 has not been taken forward beyond development of the draft protocol published and therefore the information you have requested does not exist.

Yours sincerely,

FOI Team,

Safety and Surveillance Group